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**WARNING LETTER**  
**VIA EXPRESS**

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

JUN 20 2000

Mr. Ezzat Iskander  
President  
Canix Sterilizer  
7085 Tomken Road  
Mississauga, Ontario, Canada L5S 1R7

Dear Mr. Iskander:

During an inspection of your firm located in Mississauga, Ontario, Canada, on April 27-28, 2000, our investigator determined that your firm contract sterilizes bandages for [REDACTED]. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example:
  - a. There are no established parameters and tolerances for the [REDACTED] cycle used in the sterilization of medical devices or any other product.
  - b. The content inside the cases, which is being sterilized for customers, is not always known.
  - c. The [REDACTED] *Sterilizer Equipment Records Rev. 2* states that a list of visual checks should be performed prior to running the sterilizer using form [REDACTED]. However, from October 12, 1999 to April 19, 2000, the following checklists, [REDACTED], were missing: batch #89 (3/8/00), batch #87 (2/24/00), batch #86 (2/19/00), batch #83 (2/10/00), batch #81 (1/6/00), batch #75 (11/2/99), batch #74 (10/28/00), and batch #72 (10/26/00).
2. Failure to review the associated data and documentation for finished devices prior to release, as required by 21 CFR 820.80(d)(2). For example, sterilization batch #84 (2/17/00), containing [REDACTED] pallets of [REDACTED] bulk bandages and neon bandages, was released even though the hardcopy printout showing the process parameters did not come out of the printer.

3. Failure to adequately validate with a high degree of assurance a process that cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, no documentation of a recent ETO sterilization chamber qualification or commissioning exists.
4. Failure to establish and maintain procedures for implementing corrective and preventive action, which include investigating the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, there is no written procedure that addresses how to conduct failure investigations and implement corrective and preventive corrective actions in the event of a product or ETO cycle nonconformance. An example of this is, sterilization batch #73, 10/27/99, containing [REDACTED] pallets of [REDACTED] bulk bandages and neon bandages, failed a spore strip laboratory sterility testing, and no formal documented investigation into the nonconformance was performed.
5. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, there is no documented software validation or verification for the software used in the [REDACTED] microprocessor, which is utilized in conjunction with the [REDACTED] Corporation ETO sterilizer.
6. Failure to have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed, as required by 21 CFR 820.25(a). For example, the management, including the Quality Assurance Manager, do not have sufficient Quality Systems Regulation training or experience.
7. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, there are no internal audit procedures and documented internal audits have not been conducted for the ETO sterilization operations.
8. Failure to establish and maintain procedures for changes to a method, process or procedure, as required by 21 CFR 820.70(b). For example, there are no change control procedures for the sterilization activities.
9. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups pending use or distribution, as required by 21 CFR 820.150(a). For example, there are no physical areas designated to segregate sterilized product from unprocessed non-sterile products.

10. Failure to establish and maintain process control procedures, which include documented instructions, standard operating procedures, and methods that define and control the manner of production, as required by 21 CFR 820.70(a)(1). For example, the sterilization procedure, [REDACTED], does not specify where to place the spore strip and biological indicator during routine cycles, nor has the most challenging location inside the chamber been identified.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

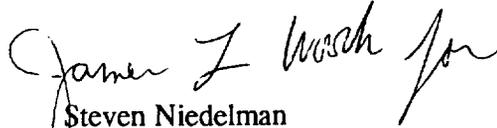
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Given the serious nature of these violations of the Act, all devices sterilized by Canix Sterilizer of Mississauga, Ontario, Canada may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove your firm and the devices, which you sterilize that may be detained from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your firm and products sterilized by your firm may resume entry into this country.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,



Steven Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

cc:

